

FDA Listed Prescription and Over-the-Counter Drug Manufacturers

Manufacturers of prescription and over-the-counter (OTC) drugs approved for the U.S. market were identified through the National Drug Code (NDC) database from the U.S. Food and Drug Administration (FDA). The analysis focused on medicines used in the home: prescription drugs that are likely used in a clinical setting were excluded, and OTC drugs that are cosmetics or personal care products were excluded. The following results reflect a best estimate of the number of manufacturers of medicines in different categories from the NDC data, as well as further analysis using FDA information, the Physician's Desk Reference for Nonprescription Drugs, and www.Drugs.com¹. The FDA's requirements for marketing of OTC drugs are less rigorous than for prescription drugs², so the number of OTC manufacturers is less certain than the number of prescription drug manufacturers.

Manufacturers of Household Medicines Approved for Sale in the U.S. by Manufacturer and Market Type

Manufacturer Type	Brand Name - only	Generic - only	Both Brand & Generic	Total # Manufacturers
Prescription	193	195	151	539
Over-the-Counter	91	6	18	115
Both Prescription & Over-the-Counter	9	11	5	25

Prescription Drugs & Manufacturers

Currently there are over 53,000 prescription drugs listed by the FDA in the NDC database, including both retail prescription and clinical use drugs.

For this analysis, manufacturers of drugs most likely used in a clinical setting, such as through epidural and intravenous routes, were excluded. Manufacturers of biologic drugs sold under prescription were included.

Over-the-Counter Drugs & Manufacturers

Currently there are over 17,000 over-the-counter (OTC) products listed by the FDA in the NDC database. OTC drugs account for six out of every ten medications bought by consumers according to the FDA³.

Additional shifts of drugs from the prescription to the OTC category are expected by 2016. Prescription drugs used primarily for chronic therapy treatment, such as hypertension, dermatology, lipid-lowering, osteoporosis, arthritis and incontinence, are expected to switch from prescription to OTC status soon.⁴

For this analysis, OTC drugs that are cosmetic or personal care products were excluded, for example wrinkle cream and toothpaste.

In addition to the 115 manufacturers of OTC drugs identified in this analysis, there are approximately 530 additional marketers of OTC drugs listed in the NDC database. OTC drug marketers include retailers, pharmacies, and other companies that put their labels on an OTC drug made by a contract manufacturer.

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¹ USFDA – National Drug Code Database. Data downloaded on July 30, 2012 at: <http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>; FDA - Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Accessed online at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>; Physician's Desk Reference for Nonprescription Drugs. 2012. PDR Ed. 33. Online reference drug database – www.Drugs.com

² FDA – OTC drug development and approval process. Accessed online at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/Over-the-CounterDrugs/default.htm>

³ FDA – OTC drug development and approval process. Accessed online at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/Over-the-CounterDrugs/default.htm>

⁴ The Pharma Letter. Accessed online August 13, 2012 at: <http://www.thepharmaletter.com/file/107173/major-global-expansion-of-rx-to-otc-switch-forecast-by-2016.html>